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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,130	09/10/2003	Christopher Patrick Lawson	GJ-246J	3558
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IANDIORIO & TESKA INTELLECTUAL PROPERTY LAW ATTORNEYS 260 BEAR HILL ROAD WALTHAM, MA 02451-1018			EXAMINER NATNITHITHADHA, NAVIN	
			ART UNIT 3735	PAPER NUMBER
			MAIL DATE 05/30/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/659,130

Applicant(s)LAWSON, CHRISTOPHER
PATRICK**Examiner**

NAVIN NATNITHADHA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 April 2008 has been entered.

Response to Amendment

2. The status of the claims is as follows:
- Claims 1-4 are currently amended;
- Claim 5 is as originally filed; and
- Claims 6-12 are cancelled.
3. The objection to amended disclosure for introducing new matter is WITHDRAWN in view of the Amendment, filed on 17 March 2008.
4. The 35 U.S.C. 112, first paragraph, rejections to claims 1-5 are WITHDRAWN in view of the Amendment, filed on 17 March 2008.
5. The objections to claim 2-4 are WITHDRAWN in view of the Amendment, filed on 17 March 2008.

Specification

6. The amendment filed 07 June 2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no

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amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

In the Amendment, filed on 17 March 2007, Applicant deleted paragraph at page 4, lines 10-13. Thus, the Applicant has changed the scope of the original disclosure, filed 10 September 2003, which constitutes new matter.

Response to Arguments

7. Applicant's arguments, see Remarks, pp. 8-11, filed 17 March 2008, with respect to the rejection of claims 1-4 under 35 U.S.C. 103(a) as being unpatentable over Holscher, U.S. Patent No. 5,630,411 A ("Holscher"), in view of Hilssman, WO-98-14115 A1 ("Hillsman"), and further in view of Minowa et al, U.S. Patent No. 4,909,212 A ("Minowa"), have been fully considered, but they are not persuasive.

Claim 1: First, Applicant asserts, see Remarks, pp. 8-9, the following:

The Applicant's original disclosure on the deleted paragraph 4 made it quite clear that the preferred shape is a triangular shape, and that other shapes (which are not preferred) may be employed if desired. The fact that other shapes may be employed if desired, does not detract from the fact that there is a clear statement that the preferred shape is triangular.

However, this argument is not persuasive. The deleted paragraph reads as follows:

The rotary variable orifice valve may have an orifice which is of a shape that causes the resistance to flow of the rotary variable orifice valve to increase with rotation. Preferably, the orifice in the rotary variable orifice valve is of a triangular shape. Other shapes may be employed if desired.

Applicant did not disclose in the original disclosure that the preferred triangular shape provides an advantage, is used for a particular purpose, or solves a stated problem. Thus, the above disclosure can only mean that the "other shapes" are equivalent. In fact, Applicant explicitly discloses that "[o]ther shapes may be employed if desired".

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Applicant stated in the Remarks, pp. 9-10, the following:

More specifically, the Applicant's triangular shape gives very good fine control of the pressure. This is because the area created by a triangular aperture and a rectangular aperture when they overlap, not only defines a triangular aperture but also the overlapping area can be very gradually increased in size from the apex of the formed triangular aperture. If two square or rectangular apertures are placed on top of one another and they are moved to define a rectangular or square opening, then the initial area of the defined overlap is much larger because it has to extend all along one side of the two overlapping square or rectangular apertures. This means that the overlapping area is much larger than with the Applicant's arrangement, and thus the degree of control is much less than that achieved with the Applicant's arrangement.

However, this stated advantage and purpose of the triangular shape is not supported by Applicant's original disclosure, and is only stated in the present Applicant's Remarks. In fact, a fair examination of Applicant's original disclosure as a whole would lead one of ordinary skill to determine that the scope of the disclosure encompasses triangular and "other" shapes. Examiner would like to remind the Applicant that inclusion of the above stated advantage and purpose in the present application would constitute new matter.

Second, Applicant asserts, see Remarks, p. 10, that the following:

Minowa was Invented in 1989. Holscher was invented In 1995 which is six years later. However, Holscher did not adopt the Minowa construction. The Holscher control is basically a coarse on/off, on/off etc. control. Holscher and anybody reading Holscher would not be looking for fine control of the type achieved with a triangular aperture. Holscher only wants on/off control in order to get the whole of the pressure applied during inhalation, and a lower pressure during the entire time of exhalation. The problems solved by Holscher and Minowa are not the same and therefore their combination would not be readily affected. Hillsman is concerned with dyspnea (breathlessness) awareness. There is no reason or instruction to combine Hillsman and Minowa in the way suggested by the Examiner.

In response to Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on the combination of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to Applicant's argument that Minowa is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the both Holscher and Minowa is directed to the area of control valve technology.

Third, Applicant asserts, see Remarks, pp. 10-11, that the

In addition to the above, it will also be noted from Figures 5 - 8, that the Holscher construction is extremely complicated. The Applicant has distinguished further over Holscher in the above amended claim 1 by specifying that it is the Applicant's sleeve which rotates on the cylindrical member. The cylindrical member acts as a bearing for the sleeve. This construction is simple and much different to that shown in Figures 5 - 8 of Holscher. The Applicant's simplicity of construction gives manufacturing and operational advantages over Holscher.

Still further, the Applicant's claim 1 has been amended to specify that the longitudinal axis of the Applicant's motor is positioned apart from the longitudinal axis of the cylindrical member. This is a yet difference which is not shown In Holscher.

However, this is not persuasive. Holscher teaches a sleeve (valve element cover) 74, which is mounted on the cylindrical member (shiftable valve element, which includes support bodies 114 and valve fingers 116) 72 and which rotates over the cylindrical member 72 (see figs. 5 and 7), and wherein the cylindrical member 72 has a

longitudinal axis, the motor 78 has a longitudinal axis, and the longitudinal axis of the motor 78 is positioned remote from the longitudinal axis and the cylindrical member 72 (see fig. 7).

Another interpretation that can be properly made, is that Holscher teaches a sleeve (shiftable valve element, which includes support bodies 114 and valve fingers 116) 72, which is mounted on the cylindrical member (upper section) 82 and which rotates over the cylindrical member 82 (see figs. 5 and 7), and wherein the cylindrical member 82 has a longitudinal axis, the motor 78 has a longitudinal axis, and the longitudinal axis of the motor 78 is positioned remote from the longitudinal axis and the cylindrical member 82 (see fig. 7).

Using either interpretation, Holscher teaches the claimed limitations at issue.

For the above reasons, the rejection of claim 1 is maintained.

Claims 2-4: Applicant stated, see Remarks, p. 11, that "the Applicant relies for the patentability of these claims 2-4 on the fact that they include all of the features of the amended claim 1". Thus, the rejection of claim 5 is maintained for the same reasons as above for claim 1.

8. Applicant's arguments, see Remarks, p. 11, filed 17 March 2008, with respect to the rejection of claim 5 under 35 U.S.C. 103(a) as being unpatentable over Holscher in view of Hillsman and Minow, and further in view of Bacaner et al, U.S. Patent No. 4,966,141 A (""), have been fully considered, but they are not persuasive.

Claim 5: Applicant stated, see Remarks, p. 11, that "the Applicant relies for the patentability of claim 5 on the fact that this claim includes all of the feature of the above

amended claim 1". Thus, the rejection of claim 5 is maintained for the same reasons as above for claim 1.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holscher, U.S. Patent No. 5,630,411 A ("Holscher"), in view of Hillsman, WO-98-14115 A1 ("Hillsman"), and further in view of Minowa et al, U.S. Patent No. 4,909,212 A ("Minowa").

Claims 1: Holscher teaches an apparatus (see figs. 1 and 5-8), comprising: a mouthpiece (inlet tube) 20/130; a flow transducer 18; a pressure transducer 16; a rotary variable orifice valve 14; a motor (valve motor) 78; and a microprocessor controller 26, wherein the microprocessor controller/circuit 26 controls the motor to cause the rotary variable orifice valve 14 to vary its orifice size in response to at least one of flow and pressure signals obtained consequent upon the person breathing into the mouthpiece (see col. 4, ll. 60-65), wherein the orifice size maintains a constant predetermined pressure (controller 26 receives signals from phase detection circuit 24, which receives a signal from the flow sensor, see col. 4, ll. 60-65) and enables measurement of the flow rate or pressure generated by the person and enables measurement of the flow rate generated by the person (matter of intended use of rotary variable orifice valve 14), and wherein the variable orifice valve 14 is a rotary variable orifice valve 14 comprising a cylindrical member (shiftable valve element, which includes support bodies 114 and

valve fingers 116) 72, a longitudinally extend bore (motor shaft) 80 in the cylindrical member 72, a first lateral aperture (exhaust ports) 122 positioned in a wall of the cylindrical member 72 and between ends of the cylindrical member 72, a sleeve (valve element cover) 74, which is mounted on the cylindrical member (shiftable valve element, which includes support bodies 114 and valve fingers 116) 72 and which rotates over the cylindrical member 72 (see figs. 5 and 7), wherein the lateral aperture 122 positioned in the wall of the cylindrical member 72 and the lateral aperture 122 positioned in the wall of the sleeve overlap and define a rectangular shape (see fig. 5), a longitudinally extending bore (upper section) 82 in the sleeve 70/74, and a second lateral aperture (recesses) 96 positioned in a wall of the sleeve between ends of the sleeve, and wherein the cylindrical member 72 has a longitudinal axis, the motor 78 has a longitudinal axis, and the longitudinal axis of the motor 78 is positioned remote from the longitudinal axis and the cylindrical member 72 (see fig. 7).

In the alternative, although “enables measurement of the flow rate or pressure generated by the person and enables measurement of the flow rate generated by the person” is a matter of intended use of Holscher’s rotary variable orifice valve 14, Hillman teaches this subject matter (see pg. 14, ll. 2-6, and pg. 15, ll. 1-6). It would have been obvious to one of ordinary skill in the art to modify Holscher’s rotary variable orifice valve to be used in Hillman’s respiratory testing apparatus in order to control breathing conditions for monitoring a patient’s respiratory parameters (see Hillman, Abstract).

In regards to the claimed limitation directed to the "sleeve", please see the above Response to Arguments, section 7 of the present Office Action, for the alternative interpretation of Holscher's teaching.

As for the limitation "wherein the lateral aperture positioned in the wall of the cylindrical member and the lateral aperture positioned in the wall of the sleeve overlap and define a triangular shape", Holscher teaches the lateral aperture 96 and the lateral aperture 122 is of a rectangular shape (see fig. 5), which, according to Applicant's original disclosure, on page 4, "Other shapes may be employed if desired".

Neither Holscher nor Hillsman teach a that a lateral aperture is of a triangular shape. However, Minowa teaches a valve apparatus structurally similar to Holscher and Hillsman, comprising a triangular shaped lateral aperture 17 of cylindrical section 15 (see figs. 9A, 9B, and 22A). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Holscher's aperture 96 to have a triangular shape because, according to Minowa, a triangular aperture (17) varies the opening (orifice) continuously, and "with such an arrangement, there is provided such an advantage that, even if the control accuracy of the motor serving as a source of operation driving force for the valve is coarse, the control accuracy of the air flow rate flowing can be secured sufficiently" (see Minowa, col. 11, ll. 13-23).

Claims 2-4: Holscher does not teach "a control circuit, the flow transducer being connected to the control circuit, the pressure transducer being connected to the orifice valve and to the control circuit, and the control circuit being connected to the microprocessor controller". Hillsman teaches an apparatus (see fig. 2), comprising: a

mouthpiece (not labeled); a flow transducer 4; a pressure transducer 5; a flat plate or rotary variable orifice valve 3 (see figs. 3A, 3B, 3C); a motor 28; a display 6 and a microprocessor controller/control circuit (computer) 14, the microprocessor controller/control circuit 14 being connected to the pressure transducer 5 and flow transducer 4. It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Holscher's microprocessor controller 26, pressure transducer 16, flow sensor 18, and orifice valve 14 to be connected to Hillsman's control circuit 14 in order to obtain, process and display respiratory data to the user of the device, such as the data shown in Figure 3 of Holscher.

Although Holscher does not explicitly teach a display means, a keyboard, and a display screen or hard copy print device, Hillsman teaches a personal computer 14, which is known in the art to comprise a display and a keyboard, connected to a pressure transducer 5, flow transducer 4 and a variable orifice 3 (see fig. 2). It is obvious to one of ordinary skill in the art to modify Holscher's pressure controller 26 to include a display and a keypad/keyboard in order to operate Holscher's apparatus. In addition, these features do not appear critical to the Applicant's invention.

9. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Holscher, as applied to claim 1 above, and further in view of either Bacaner et al, US 4,966,141 (hereinafter referred to as Bacaner).

Claim 5: Holscher does not teach the mouthpiece (inlet tube) 20/130 has a flange. However, Bacaner teaches a disposable mouthpiece 200 including a flange 203 (see

fig. 19 and col. 19, lines 52-53). Thus, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Jiang's mouthpiece to include flange as taught by Bacaner in order to provide a disposable mouthpiece that effectively engages the face of the patient surrounding the mouth (see Bacaner, col. 19, lines 55-57).

Conclusion

10. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to NAVIN NATNITHITHADHA whose telephone number is (571)272-4732. The examiner can normally be reached on Monday-Friday, 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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05/24/2007